

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/913, 139 02/09/98 ZENTGRAF H 8484-029-999

HM22/0812

EXAMINER

PENNIE & EDMONDS  
1155 AVENUE OF THE AMERICAS  
NEW YORK NY 10036-2711

NOLAN, P

ART UNIT PAPER NUMBER

1644

10

DATE MAILED:

08/12/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.	08/913,139	Applicant(s)	Zentgraf et al.
Examiner	NOLAN	Group Art Unit	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address--

### Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- Responsive to communication(s) filed on 6-1-99.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

### Disposition of Claims

- Claim(s) 1-10 is/are pending in the application.
- Of the above claim(s) 5-10 is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- Claim(s) 1-4 is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All  Some\*  None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

### Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). 2.5  Interview Summary, PTO-413
- Notice of References Cited, PTO-892  Notice of Informal Patent Application, PTO-152
- Notice of Draftsperson's Patent Drawing Review, PTO-948  Other \_\_\_\_\_

## Office Action Summary

Ar unit: 1644

**Part III DETAILED ACTION**

1. This application is a 371 of PCT/DE96/00369.

2. Claims 1-10 are pending.

3. Applicant's election of Group I, claims 1-4 in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 5-10 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

**Deposit**

4. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The monoclonal antibody recited in claim 4 is essential to the claimed invention. The reproduction of the monoclonal antibodies is an extremely unpredictable event. The monoclonal antibody ACC 2207, disclosed on page 5 of the specification, must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The instant specification does not disclose a repeatable process to obtain monoclonal antibody ACC 2207, and it is not apparent if the monoclonal antibody is readily available to the public. If the deposits have been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the monoclonal antibody has been deposited under the Budapest Treaty and that the monoclonal antibody will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample or for the enforceable life of the patent whichever is longer. See 37 CFR 1.806. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

Ar unit: 1644

Amendment of the specification to disclose the date of deposit and the complete name and address of the depository is required.

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the plasmid described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 CFR 1.801-1.809 for further information concerning deposit practice.

#### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2 rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention.

Janssen et al., (J. Biol. Chem., Vol 270, No. 19, pages 11222-11229, U) teaches they bought anti-histidine antibodies which bind a histidine portion in a fusion protein, wherein said histidine region is 6 residues long, from the company Cappel (see page 11223, in particular). The Cappel catalog #57041 (V), teaches the anti-histidine antibodies used by Janssen et al., are polyclonal. Page 11222 of the Janssen et al., teaches Janssen et al., submitted the final draft of their article to be published on February 20, 1995. Since the date of sale of the anti-histidine polyclonal antibodies would need to occur prior to the final submission of the article for publication, the sale of said antibodies would also have occurred at the latest, the date of the final submission of the article for publication, 2-20-95, more than one year prior to Applicant's effective filing date.

#### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not

Ar unit: 1644

identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-3 are rejected under 35 U.S.C. § 103 as being unpatentable over Janssen et al., (U), in view of Sevier (W).

Janssen et al., has been discussed supra.

The claimed invention in claim 3 differs from the prior art teachings only by the recitation of a monoclonal antibody which binds the histidine tagged fusion protein. However, Sevier et al. (Clin Chem. 27: 1797-1806, 1981), teach the making of monoclonal antibodies from known antigens (pg 1797, column 2, in particular) and that monoclonal antibodies are more homogenous, specific and more easily available than polyclonal antibodies (abstract, in particular).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the six histidine residue tag taught by Janssen et al., in the method taught by Sevier et al., to produce monoclonal antibodies that bind six histidine residue tagged fusion proteins with the expectation that monoclonal antibodies as taught by Sevier et al., are more specific, homogenous and more easily available than polyclonal antibodies and are therefore more useful in diagnostic assays than polyclonal antibodies.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

Serial Number: 08/913,139

5

Ar unit: 1644

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

*Patrick J. Nolan*

Patrick J. Nolan, Ph.D.  
Patent Examiner, Group 1640  
August 11, 1999